UNITED STATES DISTRICT COURT FOR THE **EASTERN DISTRICT OF ARKANSAS**



SEP 25 2014

PAT J. KING

JAMES W. McCORMACK, CLERK

V.

CASE NO. 4:14 cv 569 JLH

WRIGHT MEDICAL TECHNOLOGY, INC.; WRIGHT MEDICAL GROUP, INC.; and, JOHN DOES I-V

DEFENDANTS

COMPLAINT (WITH JOHN DOE AFFIDAVIT ATTACHED)

Plaintiff, Pat J. King, by and through their attorneys, and for their cause of action allege

as follows:

This case assigned to District Ju-	dge Holmes
	Volor
and to Magistrate Judge	VOID

PARTIES

- 1. Plaintiff is a resident of the State of Arkansas. Plaintiff Pat J. King has been injured due to a medical device manufactured by the Defendants.
- 2. Defendant Wright Medical Technology, Inc. is a Delaware corporation with its principal place of business located in Memphis, Tennessee, and as such is a citizen of the states of Tennessee and Delaware.
- 3. At all times relevant, Wright Medical Technology, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including modular prosthetic hips.
- 4. Defendant Wright Medical Group, Inc. is a corporate affiliate of Wright Medical Technology, Inc. Wright Medical Group, Inc. is a Delaware Corporation with its principal place

of business in Memphis, Tennessee and as such is a citizen of the states of Tennessee and Delaware.

- 5. John Does I-V are entities whose identities are unknown that participated in the design, marketing, sale and distribution of Wright modular prosthetic hips.
- 6. Defendants, Wright Medical Technology, Inc., Wright Medical Group, Inc., and John Does I-V are collectively referred to herein as "Wright Medical" or "Defendants."
- 7. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and were subject to and under the supervision of its Codefendants.
- 8. Upon information and belief, at all times herein mentioned, the employees of all Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of the Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such allegations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendants while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

10. Venue is proper in this district pursuant to 28 U.S.C. § 1964, et seq., because a substantial part of the events giving rise to this claim occurred in Arkansas and this district.

FACTS

- 11. On or about February 28, 2012, Plaintiff Pat King was the recipient of a defective artificial hip. The artificial hip was manufactured, marketed and distributed by Wright Medical and is generally known as the Wright Profemur TL Total Hip System. Included as modular components of the Wright Profemur TL Total Hip System were a titanium alloy (Ti6A14V) stem, a modular cobalt-chromium (CoCr) neck, and a cobalt-chromium (CoCr) femoral head.
- 12. Since 1985, Defendant, Wright Medical Technology, Inc., directly or through its parent corporation, subsidiaries or affiliates, Wright Medical Group, Inc., Wright Medical Europe, S.A., Cremascoli Ortho, Wright Cremascoli Ortho, and others, designed, manufactured, labeled, marketed, promoted, distributed, and sold in the United States the Artificial hips with modular components.
- 13. Sometime after December 13, 2000, Defendant Wright Medical Technology, Inc. began to manufacture, label, market, promote, distribute and sell in the United States the Wright Medical Profemur Hip System and its components, including the Profemur Hip System modular heads, necks and stems.
- 14. Between December 13, 2000 and August 25, 2009 the Profemur Hip System included neck and stem components made of a titanium alloy.
- 15. In August 25, 2009, Wright Medical changed the Profemur Hip System modular neck component to cobalt-chromium (CoCr) alloy.

- 16. The Profemur modular necks that made of a cobalt-chromium alloy and interface at the cobalt-chromium femoral head at the femoral head-neck junction and interface with the titanium neck at the neck-stem junction.
- 17. The femoral head-neck and neck-stem modular junctions are subject reciprocal movement which result in fretting, corrosion, metal ion release and mechanical failure.
- 18. The Wright total hip replacement prosthesis implanted in Plaintiff Pat King included the components as follows: Wright Medical Lineage/Transend Femoral Head; Wright Medical Profemur Plus CoCr Modular Neck Wright Medical Conserve Total Long Neck sleeve; Wright Medical Profemur TL Femoral Stem; Wright Medical Dynasty A-Class poly liner; and, Wright Medical Dynasty PC Shell; and, Cancellous Self-tapping Bone Screw (these forgoing components will be referenced to collectively as "Wright Implant").
- 19. The modular neck component of the Wright Implant was manufactured using a cobalt-chromium alloy and is referenced by Wright Medical as PHAC 1202 and was drawn from lot 0211188726.
- 20. The stem component of the Wright Implant was manufactured using a TiGAI4V alloy and is referenced by Wright Medical as PRTL-0024 and was drawn from lot 1420730.
- 21. The femoral head component of the Wright Implant was manufactured using a cobalt-chromium alloy and is referenced by Wright Medical as 26000021 and was drawn from lot 1409954.
- 22. Plaintiff Pat King began to experience continual and repeated problems with the hip replacement which finally resulted in an additional hip surgery on January 6, 2014 which was caused by the failure of the Wright Implant to perform as expected resulting in corrosion, metal ion release, tissue damage, inflammatory action, loss, and a complete failure of the product.

- 23. At the time of the January 6, 2014 replacement surgery performed by Dr. Lowry Barnes, it was discovered that the device had failed. Dr. Barnes found marked soft tissue reaction, marked corrosion, pseudotumor reaction, and tissue damage.
- 24. At the time this Wright Implant was sold, and then inserted in Plaintiff Pat King, it had a manufacturing defect that factually and proximately caused an injury to Plaintiff Pat King, that caused the need for another successive hip replacement surgery, constant pain and suffering, loss of mobility in the left leg and hip to an extent that Plaintiff Pat King walks with a severe limp and assistive device, is in constant pain, and a permanent total disability occurred.
- 25. This manufacturing defect resulted from an error in the manufacturing process which made this Wright Implant unsafe for consumer use and it was therefore defective in that it caused the aforementioned problems as it corroded and failed.
- 26. Conversely, the Wright Implant also suffered from a design defect in that the risks that were inherent in this product being used for hip replacement, when weighed against the utility or benefit derived from the product, indicate that liability should attach to the manufacturer because the inherent risk far outweigh any benefit which might have gained by placing this defective product in the body of Plaintiff Pat King.
- 27. Defendants were negligent in the design, manufacture, distribution and sale of the Wright Implant.
- 28. Defendants failed to warn Plaintiff Pat King of its defective implant and breached express and implied warrants that arose from the manufacturing, distribution and sale of the Wright Implant.
- 29. Plaintiff Pat King's injuries suffered were both factually and proximately caused by the defective product of the Defendants.

- 30. Plaintiff Pat King is entitled to recover damages for all special damages incurred for subsequent surgeries, rehabilitative services, follow up doctor visits and all expenditures incurred as a result of the additional operations and follow up procedures.
- 31. Plaintiff Pat King is entitled to compensation for permanent disability as a result of the failure of this hip replacement device which caused substantial injury.
- 32. Plaintiff Pat King further shows that she is entitled to recover for pain and suffering for all pain and suffering that he has incurred as a result of the defective product, the follow-up surgery, rehabilitation, and constant pain that occurs as a result of the failure of the product.
- 33. That all the aforesaid injuries and damages were caused solely and proximately by the negligence of the Defendants.

FIRST CAUSE OF ACTION PRODUCTS LIABILITY DEFECTIVE MANUFACTURING ARK. CODE ANN. § 4-86-102

- 34. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 35. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Wright Implant.
- 36. The Wright Implant that was manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective and unreasonably dangerous in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death. The product was expected to, and did, reach the end user or consumer, without substantial change in the condition in which it was sold.

- 37. As a direct and proximate result of Plaintiff Pat King's use of Defendants' Wright Implant, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- 38. Plaintiff contends that the conduct of the Defendants is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, or with reckless or conscious disregard for human life and safety, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION PRODUCTS LIABILITY DESIGN DEFECT ARK. CODE ANN. § 4-86-102

- 39. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:
- 40. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Wright Implant.
- 41. The Wright Implant, manufactured and supplied by Defendants was defective and unreasonably dangerous in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices. The product was expected to, and did, reach Plaintiff Pat King without substantial change in the condition in which it was sold.
- 42. The foreseeable risks associated with the design or formulation of the Wright Implant, include, but are not limited to, the fact that the design or formulation of the Wright

Implant is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

- 43. As a direct and proximate result of Plaintiff Pat King's use of the Wright Implant, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or their failure to comply with federal requirements, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- 44. Plaintiff contends that the conduct of the Defendants is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, or with reckless or conscious disregard for human life and safety, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION PRODUCTS LIABILITY FAILURE TO WARN ARK. CODE ANN. § 4-86-102

- 45. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 46. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Wright Implant.
- 47. The Wright Implant, manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product and/or with applicable federal requirements and Defendants failed to warn of the defects, problems, risks or hazards with its product. Defendants had a duty to warn of the risks and dangers of its products because it knew these products were being placed in the human body and could cause substantial physical harm and suffering when used in their normal

and customary manner. Defendants breached their duty, because their warning was inadequate and the breach proximately caused harm to the Plaintiff.

- 48. Defendants distributed and sold the Wright Implant in the condition in they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Wright Implant was expected to and did reach Plaintiff Pat King without substantial change or adjustment in their condition as manufactured and sold by Defendants.
- 49. The Wright Implant designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants was in a dangerous and defective condition and posed a threat to any user or consumer of the Wright Implant. Plaintiff was and is in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the Wright Implant.
- 50. The Wright Implant was implanted and used in the manner for which they were intended. This use has resulted in severe physical and emotional and other injuries to Plaintiff.
- 51. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the Wright Implant created a high risk of bodily injury and serious harm.
- 52. Defendants failed to provide adequate and timely warnings or instructions regarding the Wright Implant and its known defects.
- 53. Plaintiff Pat King and/or her physician justifiably relied upon Defendants' warnings or lack thereof regarding the Wright Implant, when they selected these products to be used in surgery.
- 54. As a direct and proximate result of Plaintiff Pat King's use of the Wright Implant, and Defendants' breach of their duty to warn of the dangers and risks regarding the character and quality of the Wright Implant and/or the failure to comply with federal requirements, Plaintiff

has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

55. Plaintiffs contend that the conduct of the Defendants is attended by circumstances of oppression, fraud, malice, or willfulness, wantonness, or with reckless or conscious disregard for human life and safety, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION NEGLIGENCE/WANTONNESS

- 56. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 57. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Wright Implant into the stream of commerce, including a duty to assure that its products did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.
- 58. Defendants have an obligation to not violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Wright Implant, and otherwise distributing the Wright Implant.
- 59. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 (a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising there from.

- 60. Plaintiff Pat King, as a purchaser of a Wright Implant, is within the class of persons the statutes and regulations are designed to protect, and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.
- 61. Defendants failed to exercise ordinary care and/or were wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the Wright Implant into interstate commerce in that Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers, and/or through failure to comply with federal requirements.
- 62. Despite the fact that Defendants knew or should have known that the Wright Implant posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Wright Implant for use by consumers and/or continued to fail to comply with federal requirements.
- 63. Defendants knew or should have known that consumers such as Plaintiff Pat King would foreseeably suffer injury as a result of Defendants failure to exercise ordinary care and/or wanton conduct as described above, including the failure to comply with federal requirements.
- 64. As a direct and proximate result of Defendants' negligence and/or wantonness, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- 65. Plaintiff contends that the conduct of the Defendants, as described above, including but not limited to their failure to adequately design and manufacture, as well as its continued marketing and distribution of the Wright Implant when they knew or should have known of the serious health risks these devices created and/or the failure to comply with federal requirements, is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, and

constitutes a conscious, reckless and flagrant disregard for human life, so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION BREACH OF EXPRESS WARRANTY ARK. CODE ANN. § 4-2-313

- 66. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 67. Defendants expressly warranted that the Wright Implant was a safe and effective orthopedic device for patients requiring a hip replacement.
- 68. The Wright Implant manufactured and sold by Defendants did not conform to these express representations, because they caused serious injury to Plaintiff Pat King when used as recommended and directed.
- 69. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
 - 70. Plaintiff has complied with the notice requirements of Arkansas warranty law.

SIXTH CAUSE OF ACTION BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARK. CODE ANN. § 4-2-313 AND ARK. CODE ANN. § 4-2-314

- 71. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.
- 72. At the time Defendants designed, manufactured, marketed, sold, and distributed the Wright Implant for use by Plaintiff Pat King, Defendants knew of the use for which the Wright Implant was intended and impliedly warranted this product to be of merchantable quality and

safe for its particular use and that their design, manufacture, labeling, and marketing complied with all applicable federal requirements.

- 73. Plaintiff Pat King and and/or her physician reasonably relied upon the skill and judgment of Defendants as to whether the Wright Implant was of merchantable quality and safe for its intended particular use and upon Defendants' implied warranty as to such matters, including that they were in compliance with all federal requirements.
- 74. Contrary to such implied warranties, the Wright Implant device was not of merchantable quality or safe for its particular intended use, because the product was defective as described above, and/or failed to comply with federal requirements.
- 75. As a direct and proximate result of Defendants' breach of warranties, Plaintiffs have suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
 - 76. Plaintiff has complied with the notice requirements of Arkansas warranty law.

SEVENTH CAUSE OF ACTION UNJUST ENRICHMENT

- 77. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.
- 78. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' Wright Implant by Plaintiff Pat King.
- 79. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff Pat King, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff Pat King was not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff Pat King, as a reasonable consumer, expected.

80. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly

enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the

disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the

extent and in the amount deemed appropriate by the Court; and such other relief as the Court

deems just and proper to remedy the Defendants unjust enrichment.

81. Plaintiff requests a trial by jury.

WHEREFORE, Plaintiff prays for an award of damages against the Defendants jointly

and severally as follows:

a. All economic, special, and compensatory damages, past and future,

recoverable by the Plaintiff under Arkansas law;

b. All non-economic and general damages, past and future, recoverable by the

Plaintiff including past and future pain and suffering and mental anguish;

c. Attorneys fees and costs;

d. Punitive damages;

e. Prejudgment and post-judgment interest; and

f. Any and all further relief, both legal and equitable, that the Court may

deem just and proper.

Respectfully submitted,

PAT J. KING, Plaintiff

Paul J. James, Arkansas Bar No.: 83091

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Attorneys for Plaintiff

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STATE OF ARKANSAS)) ss. COUNTY OF PULASKI)
<u>AFFIDAVIT</u>
Before the undersigned Notary Public, duly commissioned and acting within the County and State aforesaid, appeared in person, Paul J. James, who stated the following under oath:
1. I am an attorney licensed in the State of Arkansas.
2. This affidavit is being filed contemporaneous with a complaint pursuant to Ark Code Ann. § 16-56-125.
3. I represent Pat J. king in a potential claim against Wright Medical Technology, Inc., Wright Medical Group, Inc., and Wright Medical Supply, Inc.
4. John Does I-V are entities whose identities are unknown that participated in the design, marketing, sale and distribution of Wright Medical prosthesis devices.
5. Further affiant sayeth not. Paul J. James
SUBSCRIBED AND SWORN to before me this day of September, 2014.
My Commission Expires: 41724 Notary Public HANNAH MAXWELL MY COMMISSION # 12398373 EXPIRES: April 17, 2024 Pulaski County